

Drug Enforcement Administration Pharmaceutical Industry Conference

Wholesale Distribution Diversion Control Program

September 11, 2007

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AmerisourceBergen Corporation**

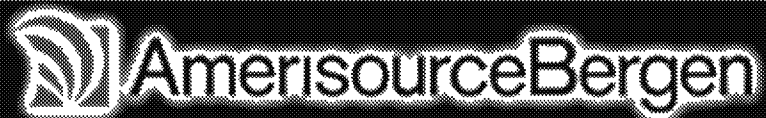
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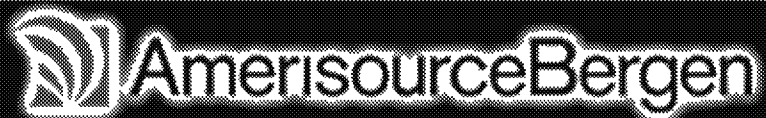
Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

1301.71(a) - "All applicants and registrants shall provide **effective controls** and procedures to **guard against theft and diversion** of controlled substances."

Distributor Response: Develop policy to

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HOW?

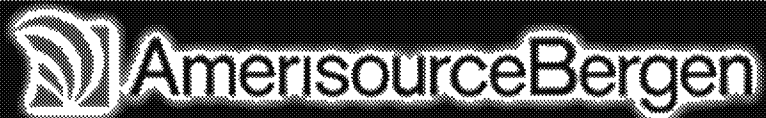
Distributors usually implement policies that mirror the Code of Federal Regulations' requirements:

1301.72 - Physical Security Controls – vault / cage construction and alarm system requirements – No Problem

1304 – Records and Reports of Registrants – information, maintenance, and inventory requirements – No Problem

1305 – Orders For Schedule I & II Controlled Substances – ordering, filling, executing, and endorsing DEA Forms 222 – No Problem

1301.74 – Other Security Controls – make a **good faith** inquiry; report suspicious orders; report **significant** losses – gray area



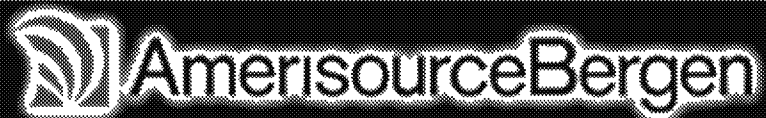
Regulatory Responsibility

Title 21 of the Code of Federal Regulations:

1301.74(b) - "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform Field Diversion Office of the Administration in his area of suspicious orders when discovered by the registrant."

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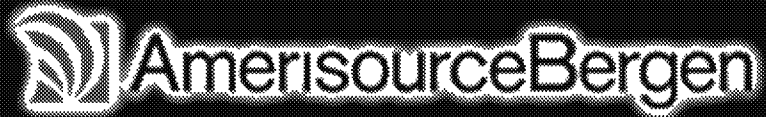


Regulatory Responsibility

- ▶ Reporting suspicious orders to DEA does NOT relieve the distributor of the responsibility to maintain effective controls to prevent diversion.
- ▶ DEA cannot / will not tell a distributor:
 - if an order is or is not legitimate; and/or
 - if the distributor should or should not ship an order
- ▶ Distributor must make a “business” decision whether or not to ship the order.

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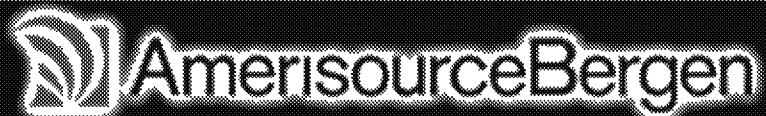


ABC's Diversion Control Program

- ▶ **“Know Your Customer” Due Diligence**
- ▶ **Order Monitoring Program (OMP)**
- ▶ **Investigations**
- ▶ **Education and Training**

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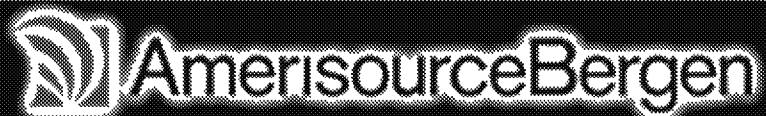
New Customer Due Diligence

- ▶ “Know Your Customer” Due Diligence investigations completed on all new Retail and Wholesale Accounts.
 - Retail chain pharmacies are exempted.

- ▶ Included in New Account Setup Process
 - New Account Questionnaire
 - On-site visit includes photographs inside and out (or physical description of premises)

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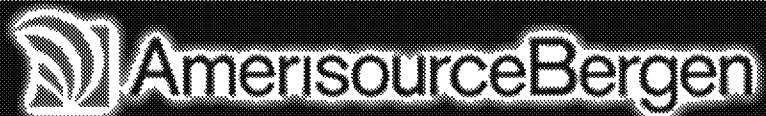
New Customer Due Diligence

- ▶ Monthly Sales Limits
 - All new accounts set at the lowest threshold level for DEA business type in ABC's Order Monitoring Program (OMP)

- ▶ "Do Not Ship" List
 - Customers to whom ABC has ceased distribution to due to suspicious activity
 - Other sources

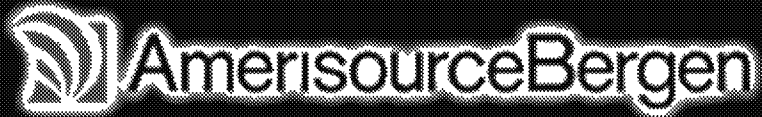
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Order Monitoring Program (OMP)

- ▶ The Controlled Substances/Listed Chemicals Order Monitoring Program (OMP) was developed to identify suspicious orders and purchasing trends.
- ▶ Historically Controlled Substance / Listed Chemical order monitoring has been based on a **ship and report** process.
- ▶ ABC's OMP process is now based on: identify, capture, investigate, and report suspicious orders; all **prior to shipment**.



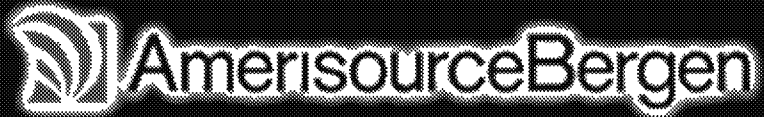
OMP Customer Account Type and Size

- ▶ Each Customer is classified by “Customer Type,” which represents how the customer is registered with DEA.
 - Hospital/Clinic, Retail Pharmacy, Distributor, etc.
 - This value is loaded using the NTIS Database synch process.

- ▶ Each customer is then categorized by “Customer Size” based upon average revenue relative to its peers in the same “Customer Type.”

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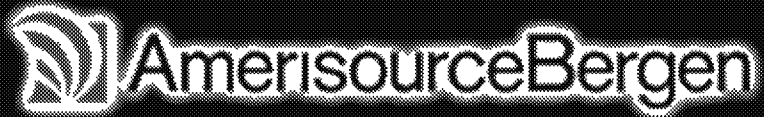


OMP Item Family and Threshold

- ▶ All controlled substance and listed chemical products are grouped into item “families” based upon the drug’s active ingredient, which has a corresponding Generic Code Number (GCN).
- ▶ The OMP will combine all sales of items within the same GCN family (e.g., hydrocodone / vicodin; oxycodone / percocet; Alprazolam / Xanax), for each customer.

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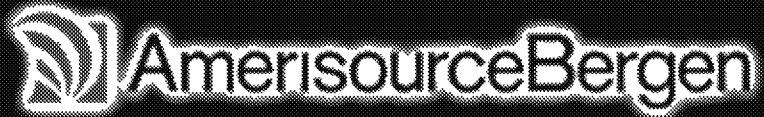


OMP Item Family and Threshold

- ▶ Item threshold levels are established from accumulated monthly sales for all customers based on item family, DEA type, and customer size.
- ▶ A customer's threshold level is initially set by item family based on the customer's DEA type and customer size.

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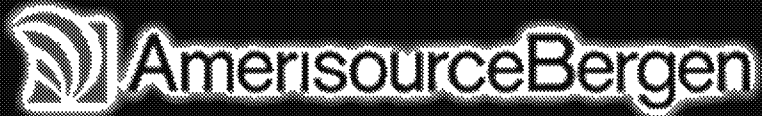


OMP Order Processing

- ▶ A customer's incoming orders are accumulated by item family, and the total item family order quantity is applied to the predetermined Item family monthly threshold.
- ▶ If the order quantity falls below the Item family threshold, the order will process normally.

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OMP Order Processing

- ▶ If the order quantity goes over the item family threshold, the order will be placed into “OMP Review.”
- ▶ All subsequent orders within the same item family will be rejected while an item within the same family is under review.
- ▶ Each distribution center (DC) is responsible for initial review of all orders in OMP Review.
 - If the DC can determine the order is not suspicious, the DC will release the order.
 - If the DC is unsure, the order will be flagged to be investigated by Corporate (CSRA).

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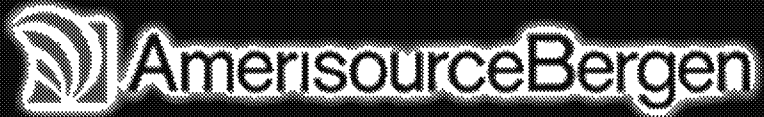


OMP Order Processing

- ▶ All OMP orders that the DC released, as well as those flagged for CSRA Review, are sent to CSRA each morning.
- ▶ Based upon information available to CSRA, flagged orders will either be released or placed in “Investigate” status.
- ▶ All orders placed into Investigate status are electronically reported to DEA on a daily basis.

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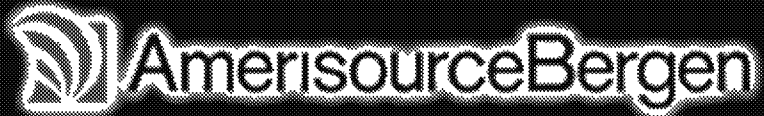
OMP Order Processing

- ▶ CSRA conducts the investigation and will notify the distribution center of the final disposition of the order (release or cancel).

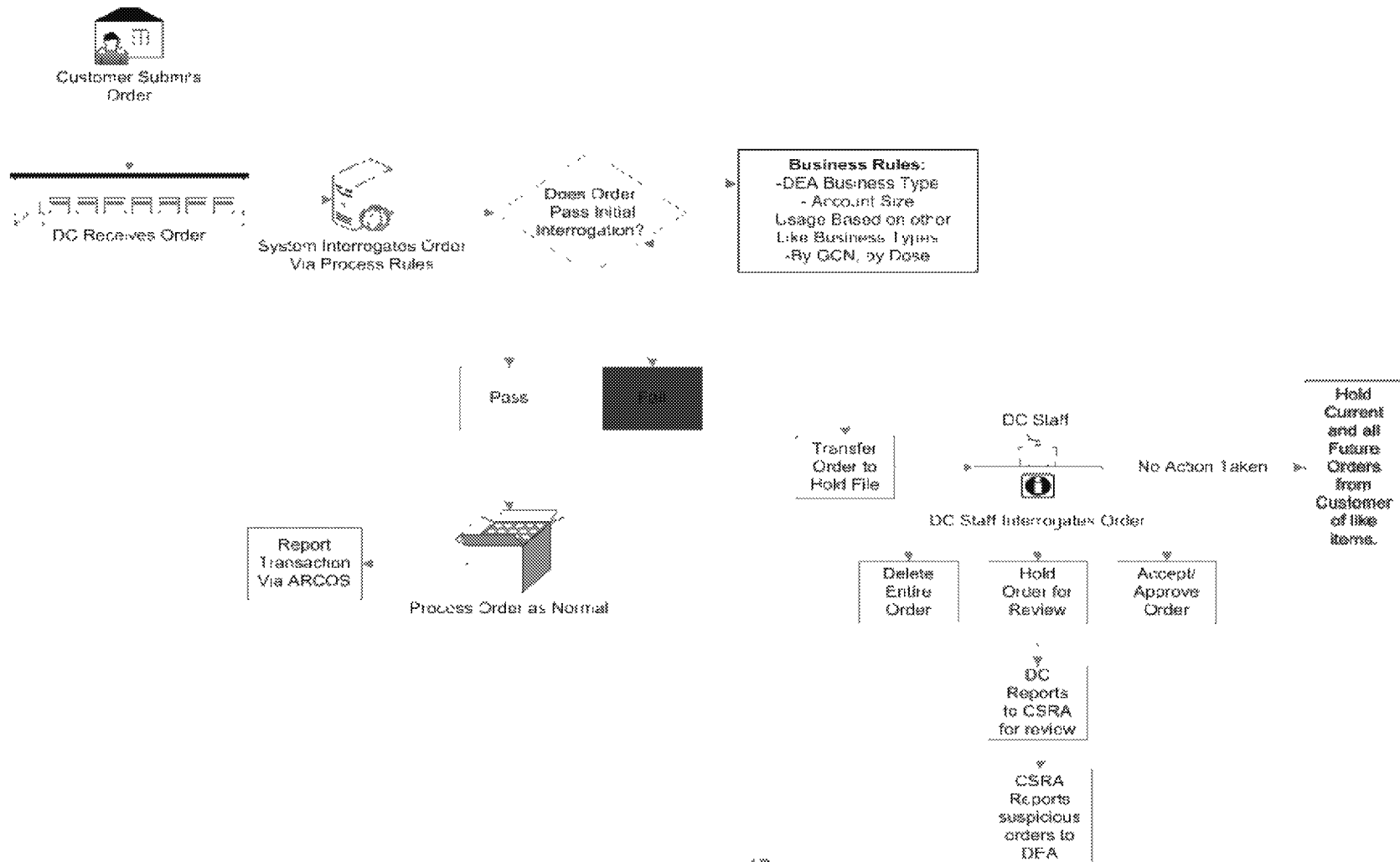
- ▶ CSRA will also determine if any permanent action needs to be taken with the customer.
 - Customers who have legitimate needs will have their size or threshold levels increased.
 - Customers with continued suspicious ordering patterns may have their ability to order control substances effected.

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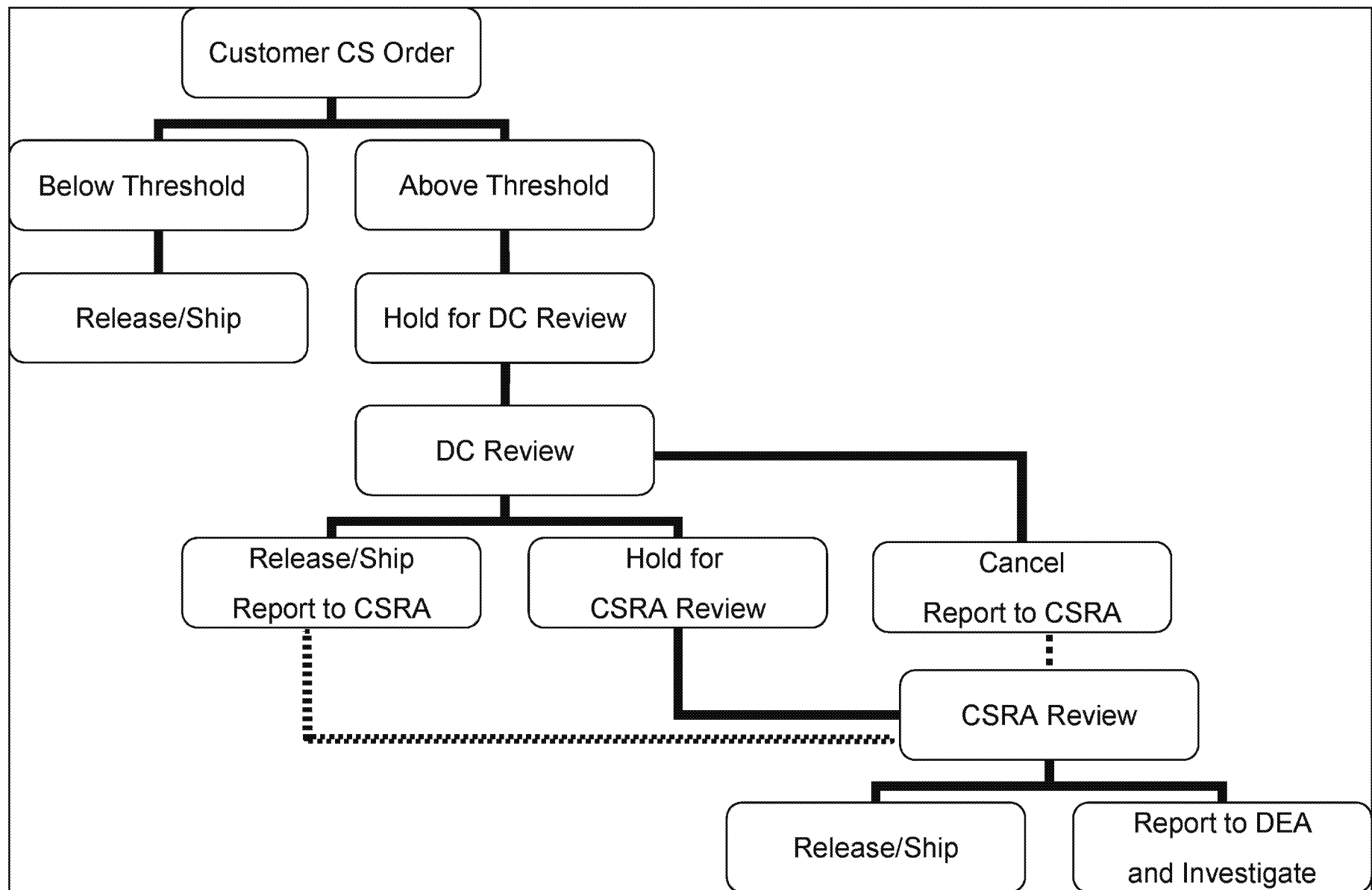
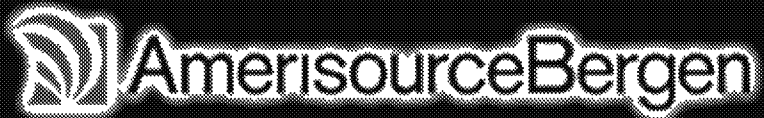


Order Monitoring Process (OMP)



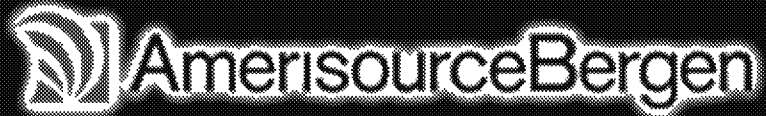
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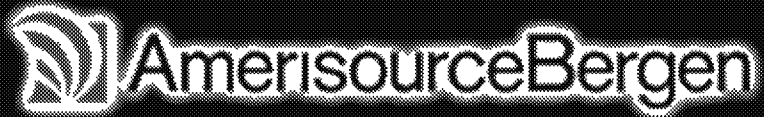


Order Monitoring Program (OMP)

- ▶ A Distributor can't solely rely on computer systems and programs to prevent diversion.
- ▶ All employees have a role and responsibility in a successful Order Monitoring Program:
 - Sales
 - Procurement
 - Management (DC / HQ)
 - Order fillers
 - Customer service
 - IT

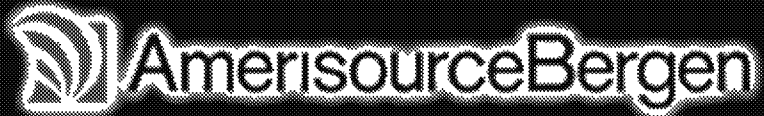
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Investigations

- ▶ Sources of Investigations
 - Order Monitoring Program (OMP)
 - Monthly Customer Product Mix Report
 - Notification by DEA
 - Notification by ABC DC
- ▶ Typical Investigation Process
 - One-year purchase history
 - On-site inspection
 - **CSRA Form 590c Retail Pharmacy Verification Checklist**
- ▶ Decision
 - Cease distribution of CS/LC to customer
 - Customer Sign applicable compliance agreement



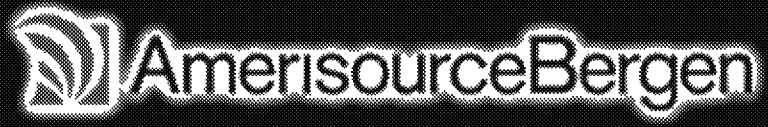
Education and Training

- ▶ All appropriate associates are trained on ABC's Diversion Control Program
- ▶ ABC also holds training and educational courses for its customers and vendors regarding this subject matter.



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Questions?

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